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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.**	**Applicant(s)**	
	10/538,011	GRUND-PEDERSEN ET AL.	
	Examiner	**Art Unit**	
	BRUK A. GEBREMICHAEL	3715	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-24,26,27,29 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13-24,26,27,29 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/04/2011*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/26/2010 has been entered.

2. Currently claims 1, 13, 20, 22, 24, 26 and 29, have been amended; claims 12, 25, 28 and 30 have been canceled; and new claim 31 has been added. Therefore, claims 1-11, 13-24, 26-27, 29 and 31 are pending in this application.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- Claims 1-11, 13-24, and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson 2002/0168618 in view of Alexander 6,929,481 and further in view of Messner 5,987,960.

Regarding claim 1, Anderson discloses the following claimed limitations, an interventional procedure simulation system, having a control unit and an interface unit (FIG 4), said control unit communicating with said interface unit to simulate handling of

a number of real nested instruments simultaneously interfaced by said interface unit (Para.0018) and, said instruments being arranged to move and rotate independently of each other and said movements and rotations being propagated to the other instruments (Para.0018 and Para.0035), said control unit including an instruction set comprising a first instruction set for handling and processing an input from a user based on said input, generating a second instruction set for controlling said interface (Para.0125, lines 7-14), a first data set comprising characteristics for said instruments (Para.0084, lines 10-16 and Para.0125, lines 17-19), a second data set comprising data on a body part to be simulated (Para.0033, lines 1-6 and Para.0124, lines 5-9), a third instruction set for generating control signals relating to an interaction between said simulated instruments and a surrounding geometry relating to a part of said simulated body part (Para.0125, lines 19-21).

Anderson further discloses, a fifth instruction set for calculating an effect of a first instrument inserted into a second instrument in a nested manner (Para.0035 and Para.0036), each instrument having properties, being at least one of a natural shape, stiffness, length, diameter and radioopacity (Para.0071), said instruction set being configured to calculate movements of said first instrument propagated to the second instrument (FIG 5B and Para.0120), a sixth instruction set for modeling a color agent which calculates behavior of said color agent and keeps track of a position currently having enough concentration of contrast to be visualized (Para.0107 and Para.0202).

Anderson does not explicitly disclose, a fourth instruction set for controlling movements of a number of serially arranged and interconnected carriages

corresponding to movements of said instruments in said interface unit, each carriage comprising: members to receive and lock at least one of the instruments, and members for receiving a movement from an instrument dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic, a detecting arrangement for detecting the type of the instruments inserted through an interconnecting member, means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member, configured to detect presence of at least one instrument in the carriage, said detecting member being arranged to detect the thickness of each instrument.

However, Alexander discloses an interface device and method in medical procedure simulation that teaches, a fourth instruction set for controlling movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface unit (see col.22, lines 5-18 and also FIG 16), each carriage comprising members to receive and lock at least one of the instruments, and members for receiving a movement from an instrument dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic (col.22, lines 21-39), a detecting arrangement for detecting the type of the instruments inserted through an interconnecting member (col.6, lines 55-63 and col.22, lines 58-67), means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator (col.18, lines 39-50 and col.23, lines 32-39).

In an alternative embodiment, Alexander further teaches, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member, configured to detect presence of at least one instrument in the carriage (col.10, lines 57-67 and col.11, lines 1-7).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander by incorporating a plurality of carriage assemblies in order to manipulate and control several nested instruments, such as wire, catheter and sheath assembly so that the user would learn the proper procedural steps for implementing a given medical procedure.

Anderson in view of Alexander does not explicitly teach, said detecting member being arranged to detect the thickness of each instrument.

However, Messner discloses a tool calibrator system that is arranged to detect thickness of instruments (col.2, lines 44-57).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander and further in view of Messner by incorporating a suitable tool calibrator into the system in order to measure the diameter of the various tools being used before performing a given medical procedure so that the user would learn the type and size of the different surgical tools needed for the different medical procedures.

Anderson in view of Alexander and further in view of Messner teaches the claimed limitations as discussed above. Anderson further discloses,

Regarding claim 2, said interventional procedure is at least one of a diagnostic, a cardiovascular or endovascular simulation system (see Abstract lines 5-8 and Para.0012, lines 1-4),

Regarding claim 3, a user's movements of said instruments, a surrounding simulated anatomy and other present instruments, affect a shape of an instrument simulated and displayed (Para.0020 and Para.0149, lines 6-12),

Regarding claim 4, each instrument collisions with simulated surrounding calculations are executed by said control unit, which affects the shape and position of said instrument in said simulated body part (Para.0205 and Para.0206, lines 1-8),

Regarding claim 5, wherein an instrument is a distal part of a tool or an end of a tool (Para.0036, lines 1-10),

Regarding claim 6, wherein different instrument types can be used comprising at least one of balloons, stems, electrodes, wires, catheters, and distal protection(Para.0018, lines 3-8),

Regarding claim 7, wherein each instrument type has different properties associated to it and provided as an instruction set, which describes substantially all properties of said instrument (see e.g. Para.0084, lines 10-16 and Para.0157, lines 1-9),

Regarding claims 8 and 9, the properties of said instruments further describe interaction with at least one of surrounding geometry, visual properties, stiffness, and shape; and wherein simulated properties of said instrument are altered in real-time (Para.0034, lines 3-13),

Regarding claim 10, the system comprises a model used for rendering objects depending on properties to be displayed and a collision model for computing collisions between the simulated instrument and body part (Para.0200 and Para.0205),

Regarding claim 11, a model of said body or part of said body part is a three-dimensional data obtained through a body scanning (Para.0021, lines 1-3 and Para.0128, lines 1-4).

Regarding claim 13, Anderson discloses the following claimed limitations: a method for simulating an interventional procedure (Para.0032, lines 1-8), comprising the steps of providing a control unit and an interface unit (FIG 4), said control unit communicating with said interface unit to simulate handling of a number of nested real instruments simultaneously interfaced by said interface unit (Para.0018) and that each nested tool is configured to be moved and rotated independently of the other and said movements and rotations are propagated to other instruments (Para.0035), providing a first instruction set for handling and processing input from a user, generating a second instruction set based on said input, for controlling said interface (Para.0125, lines 7-14), retrieving information on said instrument comprising a first data set comprising characteristics for said instruments (Para.0084, lines 10-16 and Para.0156), providing a second data set comprising data on a body part to be simulated (Para.0033, lines 1-6, and Para.0124, lines 5-9), and generating control signals relating to interaction between said instrument and a surrounding geometry by a third instruction set (see Para.0034, lines 3-10 and Para.0125, lines 19-21).

Anderson further discloses, calculating an effect of a first instrument inserted into a second instrument in a nested manner (Para.0035 and Para.0036) each instrument having properties, being at least one of a natural shape, stiffness, length, diameters and radioopacity (Para.0071) and calculating movements of said first instrument propagated to the second instrument (FIG 5B and Para.0120), modeling a color agent by calculating behavior of said color agent and keeps track of a position currently having enough concentration of contrast to be visualized (Para.0107 and Para.0202).

Anderson does not explicitly disclose, said interface unit including an instruction set for controlling movements of a number of serially arranged and interconnected carriages, corresponding to movements of said instruments in said interface device each carriage comprising members to receive and lock at least one of the instruments, and members for receiving a movement from the instrument dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic, a detecting arrangement for detecting the type of the instruments inserted through an interconnecting member, means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator, said detecting member being arranged to detect the thickness of each instrument.

However, Alexander teaches, an interface unit including an instruction set for controlling movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface unit/device (col.22, lines 5-18 and FIG 16), each carriage comprising members to receive and lock at least one of the instruments, and members for receiving a movement from the instrument

dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic (see e.g. col.22, lines 21-39), a detecting arrangement for detecting the type of the instruments inserted through an interconnecting member (see col.6, lines 55-63 and col.22, lines 58-67), means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator (col.18, lines 39-50 and col.23, lines 32-39).

Alexander in an alternative embodiment further teaches, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member, configured to detect presence of at least one instrument in the carriage (col.10, lines 57-67 and col.11, lines 1-7).

Therefore, here also, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander by incorporating a plurality of carriage assemblies in order to manipulate and control several nested instruments, such as wire, catheter and sheath assembly so that the user would learn the proper procedural steps to carry out a given medical procedure.

Anderson in view of Alexander does not explicitly teach, said detecting member being arranged to detect the thickness of each instrument.

However, Messner discloses a tool calibrator system that is arranged to detect thickness of instruments (col.2, lines 44-57).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of

Alexander and further in view of Messner by incorporating a suitable tool calibrator into the system in order to measure the diameter of the various tools being used before performing a given medical procedure so that the user would learn the type and size of the different surgical tools needed for the different medical procedures.

Anderson in view of Alexander and further in view of Messner teaches the claimed limitations as discussed above. Anderson further discloses,

Regarding claim 14, changing instrument simulated and displayed based on a user's movements of said instruments, a surrounding simulated anatomy and other present instruments, effect a shape of an instrument simulated and displayed (Para.0020, lines 7-16 and Para.0034, lines 3-13),

Regarding claim 15, wherein an instrument is a distal part of a tool or an end of a tool (Para.0036, lines 1-10),

Regarding claim 16, wherein different instrument types can be used comprising at least one of balloons, stents, electrodes, wires catheters, and distal protection (Para.0018, lines 3-8),

Regarding claim 17, wherein each instrument type has different properties associated to it and provided as an instruction set, which describes substantially all properties of said instrument (Para.0084, lines 10-16 and Para.0157, lines 1-9),

Regarding claim 18, wherein the properties of said instruments further describe interaction with at least one of surrounding geometry, visual properties, stiffness, and shape etc (Para.0035 and Para.0157, lines 9-13),

Regarding claim 19, wherein simulated properties of said instruments are altered in real-time (Para.0020, lines 7-14 and Para.0036, lines 6-16).

Regarding claim 20, Alexander discloses the following claimed limitations: a system for an interventional procedure simulation, said system having a control unit and an interface unit (FIG 4), the system further comprising a communication interface configured to communicate between said control unit and said interface unit, a simulation arrangement in said interface unit configured simultaneously simulate handling of a number of nested instruments interface by said interface unit, each said instruments being, independently movable and rotatable (Para.0018; Para.0035 and Para.0157, lines 9-12), a user input interface member configured to receive input from a user including an instruction set, a computer configured to handle and process said input (Para.0020, lines 7-14 and Para.0022), an interface control arrangement (Para.0022, lines 1-9), a first database configured to store characteristics for said instruments (Para.0084, lines 10-16 and also Para.0125, lines 17-19), a second database configured to store characteristics about a body part to be simulated (Para.0033, lines 1-6 and Para.0124, lines 5-10), and a signal generating arrangement configured to generate control signals relating to an interaction between said simulated instruments and a surrounding geometry relating to a part of said simulated body part (Para.0034, lines 3-10 and Para.0125, lines 19-21).

Anderson further discloses, a computer configured to simulate an effect of a first instrument inserted into a second instrument in a nested manner (Para.0035 and Para.0036), each instrument having properties, being at least one of a natural shape,

stiffness, length, diameter, and radioopacity (Para.0071), said instruction set being configured to calculate movements of said first instrument propagated to other second instrument (Para.0084), and modeling a color agent and calculating a behavior of said color agent and keep track of a position currently having enough concentration to be visualized (Para.0107 and Para.0202). .

Anderson does not explicitly disclose, a controller configured to control movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface device, each carriage comprising members to receive and lock at least one of the instruments, and members for receiving a movement from the instrument dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic, a detecting arrangement for detecting the type of the instruments inserted through an interconnecting member, means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator, a crank block, arranged on a torque wheel, an outlet, which is provided with a detecting member, configured to detect a presence of at least one instrument in the carriage, said detecting member being arranged to detect the thickness of each instrument.

However, Alexander teaches, a controller configured to control movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface device (col.22, lines 5-18 and FIG 16), each carriage comprising members to receive and lock at least one of the instruments, and members for receiving a movement from the instrument dummy and generating a force

fed back to the instrument dummy with respect to a simulation characteristic (col.22, lines 21-39), a detecting arrangement for detecting the type of the instruments inserted through a interconnecting member (col.6, lines 55-63 and col.22, lines 58-67), means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator (col.18, lines 39-50 and col.23, lines 32-39).

In an alternative embodiment, Alexander further teaches, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member, configured to detect a presence of at least one instrument in the carriage (col.10, lines 57-67 and col.11, lines 1-7).

Therefore, here also, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander by incorporating a plurality of carriage assemblies in order to manipulate and control several nested instruments, such as wire, catheter and sheath assembly so that the user would learn the proper procedural steps to carry out a given medical procedure.

Anderson in view of Alexander does not explicitly teach, said detecting member being arranged to detect a thickness of each instrument.

However, Messner discloses a tool calibrator system that is arranged to detect thickness of instruments (col.2, lines 44-57).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander and further in view of Messner by incorporating a suitable tool calibrator into

the system in order to measure the diameter of the various tools being used before performing a given medical procedure so that the user would learn the type and size of the different surgical tools needed for the different medical procedures.

Regarding claim 21, Anderson in view of Alexander and further in view of Messner teaches the claimed limitations as discussed above.

Anderson further discloses, said characteristics about a body part to be simulated are obtained through a scanning process (Para.0021, lines 1-3 and Para.0128, lines 1-4).

Regarding claim 22, a computer program for interventional procedure simulation in a system having a control unit and an interface unit (FIG 4), said program comprising a communication instruction set for communication between said control unit a and said interface unit (Para.0114, lines 1-6 and FIG 3), a first instruction set for simulating handling of a number of simulated nested instruments, independently movable and rotatable, simultaneously interfaced by said interface unit (Para.0018 and Para.0035), said control unit including an instruction set comprising a second instruction set for handling and processing input from a user, a third instruction set for controlling said interface (Para.0125, lines 7-14), a first data set comprising characteristics for said instruments (Para.0084, lines 10-16 and Para.0156), a second data set comprising data on a body part to be simulated (Para.0033, lines 1-6 and Para.0124, lines 5-9), a fourth instruction set for generating control signals relating to an interaction between said simulated nested instruments and a surrounding geometry relating to a part of said

simulated body part (Para.0125, lines 19-21), and a seventh instruction set for outputting simulation on a visualization member (Para.0097, lines 4-10).

Anderson further discloses, a sixth instruction set for outputting calculating an effect of a first instrument inserted into a second instrument in a nested manner (Para.0035 and Para.0036), each instrument having properties, being at least one of a natural shape, stiffness, length, diameter and radioopacity (Para.0071), said sixth instruction set being configured to calculate movements of said first instruction instrument propagated to the second instrument (FIG 5B and Para.0120), and an eighth instruction set for modeling a color agent which calculates a behavior of said color agent and keeps track of a position currently having enough concentration of contrast to be visualized (Para.0107 and Para.0202).

Anderson does not explicitly disclose, a fifth instruction set for controlling movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface device, each carriage comprising members to receive and lock at least one of the instruments, and members for receiving a movement from the instrument dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic, a detecting arrangement for detecting the type of the instruments inserted through an interconnecting member, means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member,

configured to detect presence of at least one instrument in the carriage, said detecting member being arranged to detect the thickness of each instrument.

However, Alexander teaches, an instruction set for controlling movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface device (col.22, lines 5-18 and FIG 16), each carriage comprising members to receive and lock at least one of the instruments, and members for receiving a movement from the instrument dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic (col.22, lines 21-39), a detecting arrangement for detecting the type of the instruments inserted through an interconnecting member (col.6, lines 55-63 and col.22, lines 58-67), means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator (col.18, lines 39-50 and col.23, lines 32-39).

In an alternative embodiment, Alexander further teaches, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member, configured to detect presence of at least one instrument in the carriage (col.10, lines 57-67 and col.11, lines 1-7).

Therefore, here also, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander by incorporating a plurality of carriage assemblies in order to manipulate and control several nested instruments, such as wire, catheter and sheath assembly so that the user would learn the proper procedural steps to carry out a given medical procedure.

Anderson in view of Alexander does not explicitly teach, said detecting member being arranged to detect the thickness of each instrument.

However, Messner discloses a tool calibrator system that is arranged to detect thickness of instruments (col.2, lines 44-57).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander and further in view of Messner by incorporating a suitable tool calibrator into the system in order to measure the diameter of the various tools being used before performing a given medical procedure so that the user would learn the type and size of the different surgical tools needed for the different medical procedures.

Regarding claim 23, Anderson in view of Alexander and further in view of Messner teaches the claimed limitations as discussed above.

Anderson further discloses, a program storage device readable by a machine and encoding a program of instructions for executing the computer program for interventional procedure simulation according to claim 22 (Para.0006 and Para.0125, lines 1-7).

Regarding claim 24, Anderson discloses the following claimed limitations; a computer readable medium having computer readable program code embodied therein to enable an interventional procedure simulation in a system (Para.0006 and Para.0125, lines 1-7) comprising a control unit and an interface unit (FIG 4), said program comprising a communication instruction set for communication between said control unit and said interface unit (Para.0114 and FIG 3), a first instruction set for simulating

handling of a number of simulated nested instruments, independently movable and rotatable, simultaneously interfaced by said interface unit (Para.0018 and Para.0035), said control unit further including an instruction set comprising a second instruction set for handling and processing input from said user, a third instruction set for controlling said interface (Para.0125 lines 7-14), a first data set comprising characteristics for said instruments (Para.0084, lines 10-16 and Para.0156), a second data set comprising data on a body part to be simulated (Para.0033, lines 1-6, and Para.0124, lines 5-9), a fourth instruction set for generating control signals relating to an interaction between said simulated nested instruments and a surrounding geometry relating to a part of said simulated body part (Para.0033, lines 1-6 and Para.0124, lines 5-9), a fifth instruction set for calculating an effect of a first instrument inserted into a second instrument in a nested manner (Para.0035 and Para.0036), each instrument having properties, being at least one of a natural shape, stiffness, length, diameter and radioopacity (Para.0071), said fifth instruction set being configured to calculate movements of said first instrument propagated to the second instrument (FIG 5B and Para.0120), a sixth instruction set for outputting simulation on a visualization member (Para.0097, lines 4-10), and a seventh instruction set for modeling a color agent which calculates a behavior of said color agent and keeps track of a position currently having enough concentration of contrast to be visualized (Para.0107 and Para.0202).

Anderson does not explicitly teach, the interface unit having a plurality of carriages, each carriage comprising members to receive and lock at least one of the instruments, and members for receiving a movement from the instrument dummy and

generating a force fed back to the instrument dummy with respect to a simulation characteristic, a detecting arrangement for detecting the type of the instruments inserted through an interconnecting member, means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member, configured to detect presence of at least one instrument in the carriage, said detecting member being arranged to detect the thickness of each instrument.

However, Alexander teaches, an interface unit having a plurality of carriages, each carriage comprising members to receive and lock at least one of the instruments, and members for receiving a movement from the instrument dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic (col.22, lines 21-39), a detecting arrangement for detecting the type of the instruments inserted through an interconnecting member (col.6, lines 55-63 and col.22, lines 58-67), means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator (see e.g. col.18, lines 39-50 and col.23, lines 32-39).

In an alternative embodiment, Alexander further teaches, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member, configured to detect presence of at least one instrument in the carriage (col.10, lines 57-67 and col.11, lines 1-7).

Therefore, here also, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander by incorporating a plurality of carriage assemblies in order to manipulate and control several nested instruments, such as wire, catheter and sheath assembly so that the user would learn the proper procedural steps to carry out a given medical procedure.

Anderson in view of Alexander does not explicitly teach, said detecting member being arranged to detect the thickness of each instrument.

However, Messner discloses a tool calibrator system that is arranged to detect thickness of instruments (col.2, lines 44-57).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander and further in view of Messner by incorporating a suitable tool calibrator into the system in order to measure the diameter of the various tools being used before performing a given medical procedure so that the user would learn the type and size of the different surgical tools needed for the different medical procedures.

Regarding claim 26, a system for an interventional procedure simulation, said system including a control unit and an interface unit (FIG 4), the system comprising a communication arrangement configured to control communication between said control unit and said interface unit for receiving at least two nested instruments including a first instrument inserted into a second instrument, used in said interventional procedure (Para.0018 and Para.0035-Para.0036), a computer configured to receive three-

dimensional information on a body part to be simulated (Para.0021, lines 1-3 and Para.0128, lines 1-4), an arrangement configured to generate control signals relating to an interaction between said first and second instruments and a surrounding geometry relating to a part of said simulated body part (see FIG 5B, Para.0120 and Para.0125, lines 19-21), and said control unit controls modeling a color agent by calculating behavior of said color agent and keeps track of a position currently having enough concentration of contrast to be visualized (Para.0107 and Para.0202).

Anderson does not explicitly disclose, the control signals being configured to control movements of a number of serially arranged and interconnected carriages corresponding to movements of said instruments in said interface device with respect to movements of said first instrument propagated to the second instrument, each carriage comprising members to receive and lock at least one of the instruments, and members for receiving a movement from an instrument dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic, a detecting arrangement for detecting the type of the instruments inserted through an interconnecting member, means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member, configured to detect the presence of at least one instrument in the carriage, said detecting member being arranged to detect the thickness of each instrument.

However, Alexander teaches, control signals configured to control movements of a number of serially arranged and interconnected carriages corresponding to

movements of said instruments in said interface device with respect to movements of said first instrument propagated to the second instrument (col.16, lines 54-67 and col.22, lines 5-18 and FIG 16), each carriage comprising members to receive and lock at least one of the instruments, and members for receiving a movement from an instrument dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic (col.22, lines 21-39), a detecting arrangement for detecting the type of the instruments inserted through an interconnecting member (col.6, lines 55-63 and col.22, lines 58-67), means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator (col.18, lines 39-50 and col.23, lines 32-39).

In an alternative embodiment, Alexander further teaches, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member, configured to detect the presence of at least one instrument in the carriage (col.10, lines 57-67 and col.11, lines 1-7).

Therefore, here also, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander by incorporating a plurality of carriage assemblies in order to manipulate and control several nested instruments, such as wire, catheter and sheath assembly so that the user would learn the proper procedural steps to carry out a given medical procedure.

Anderson in view of Alexander does not explicitly teach, said detecting member being arranged to detect the thickness of each instrument.

However, Messner discloses a tool calibrator system that is arranged to detect thickness of instruments (col.2, lines 44-57).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Anderson in view of Alexander and further in view of Messner by incorporating a suitable tool calibrator into the system in order to measure the diameter of the various tools being used before performing a given medical procedure so that the user would learn the type and size of the different surgical tools needed for the different medical procedures.

Regarding claim 27, Anderson in view of Alexander and further in view of Messner teaches the claimed limitations as discussed above.

Anderson further discloses, said three-dimensional in formation is obtained through a scanning process (see Para.0021, lines 1-3 and Para.0128, lines 1-4).

- Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander 6,929,481 in view of Messner 5,987,960 and further in view of Anderson 2002/0137014 .

Regarding claim 29, Alexander discloses the following claimed limitations; a method of testing new tools for an interventional procedures (col.5, lines 54-61), using a system including a control unit and an interface unit (FIG 9, labels 28, 24 and 314), the method comprising prototyping a real nested interventional procedure tool, including a first tool inserted into a second tool to be simulated in said interface device (FIG 10, labels 302, 304 and 306), said interface unit including a plurality of carriages, each carriage comprising members to receive and lock at least one of the instruments, and

members for receiving a movement from the instrument dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic (col.22, lines 21-39), a detecting arrangement for detecting the type of the instruments inserted through a interconnecting member (col.6, lines 55-63 and col.22, lines 58-67), means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator (col.18, lines 39-50 and col.23, lines 32-39).

In an alternative embodiment Alexander further discloses, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member, configured to detect presence of at least one instrument in the carriage (see col.10, lines 57-67 and col.11, lines 1-7), simulating an interaction between said nested first and second tools independently movable and rotatable, and a surrounding geometry relating to a part of said simulated body part, and using said simulation for training a user (col.16, lines 54-67).

Alexander does not explicitly disclose, said detecting member being arranged to detect the thickness of each instrument; and measuring usability of new features related to said prototyped tool, and comparing results to predefined values and providing objective measurements on interactions between a user and the prototyped tool.

However, Messner discloses a tool calibrator system that is arranged to detect thickness of instruments (col.2, lines 44-57).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Alexander in view of Messner by incorporating a suitable tool calibrator into the system in order to measure the

diameter of the various tools being used before performing a given medical procedure so that the user would learn the type and size of the different surgical tools needed for the different medical procedures.

Alexander in view of Messner does not explicitly teach, measuring usability of new features related to said prototyped tool, and comparing results to predefined values and providing objective measurements on interactions between a user and the prototyped tool.

However, Anderson discloses a simulation method for designing devices that teaches, measuring usability of new features related to said prototyped tool (Para.0012, lines 9-13 and Para.0013), and comparing results to predefined values and providing objective measurements on interactions between a user and the prototyped tool (Para.0014 and Para.0015).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of this invention was made to modify the invention of Alexander in view of Messner and further in view of Anderson by incorporating a database into the system that comprises various selectable device parameters (such as shape, material, flexibility, etc.), in order to allow the user to design a particular medical device that is most appropriate for a particular medical procedure (e.g. designing a new catheter by modifying its geometry and flexibility to make it more suitable for a particular body cavity) so that the user would be able to perform a given medical procedure safely and more efficiently.

- Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson 2002/0168618 in view of Alexander 6,929,481, in view of Messner 5,987,960 and further in view of Suri 6,842,638.

Regarding claim 31, Anderson in view of Alexander and further in view of Messner teaches the claimed imitations as discussed above.

Anderson in view of Alexander and further in view of Messner does not explicitly teach, a mapping table executed in a pre-processor.

However, Suri discloses an angiography method and apparatus that teaches, a mapping table executed in a pre-processor (col.6, lines 12-23; col.7, lines 66-67 and col.8, lines 1-7).

Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention was made, to modify the invention of Anderson in view of Alexander, in view of Messner and further in view of Suri by incorporating a pre-processor into the system, in order to remove unnecessary noise in the simulated image (such as non-vascular contrast that interferes with the vascular image) so that the required part in the body cavity would be represented by high intensities; thereby helping the user (trainee) to perform the medical procedure accurately.

Note that the above limitation is further suggested by Anderson (e.g. see Para.0107).

Response to Arguments.

5. Applicant's arguments filed on 11/26/2010 have been fully considered. In the remarks, Applicant argues that

(1) In an effort to overcome the admitted deficiency, it is alleged that one of skill in the art would have modified Anderson the system of Anderson according to the teachings of Alexander. Specifically, it is alleged that one of skill would have modified Anderson to include the interface device for accommodating and controlling nested instruments as described at column 22, lines 5-18 of Alexander. . . .

However, Anderson has force feedback devices (see Figs. 7a, 7b) that are specifically designed to work with the device. Therefore, it is unclear why or how one of skill in the art would modify the interface 5 (which is housed in the manikin 6) to include the device of Alexander. In other words, as there is no problem indicated with the device of Anderson, there is no motivation or suggestion to modify according to Alexander . . .

- In response to argument (1), the Examiner respectfully disagrees. It appears that Applicant has misunderstood the motivation for combing the references (Anderson in view of Alexander). Note that even if Anderson has a force feed back mechanism, the functions of this mechanism is to provide resistance to the forward motion of the medical device when the user (e.g. trainee) manipulates the medical device on the simulated body cavity (e.g. see Para.0032, lines 8-15 and also Para.0088). That means, the force feedback mechanism of Anderson's system is not utilized or arranged, for example, for controlling movements of serially arranged and interconnected carriages; rather, according to the embodiments depicted in FIG 7A and FIG 7B, the force feedback mechanism is described in relation to a single medical device.

As already indicated in the previous office action (and also in this current office Action), Alexander also implements a force feedback mechanism to simulate the forces encountered by the user when he/she performs a given medical procedure using

medical instruments (e.g. see col.11, lines 45-51 and col.21, lines 26-39). Alexander further describes an alternative embodiment that implements an interface device configuration that allows nested instruments and plurality of carriage assemblies to be accommodated (e.g. see col.21, lines 40-47 and col.22, lines 5-24).

However, Anderson (unlike Alexander) appears to be silent regarding such a configuration that allows the accommodation of serially arranged and interconnected carriages corresponding to movements of instruments in an interface unit.

Therefore, one of ordinary skill in the art, at the time of the invention was made, would be motivated to modify the system of Anderson based on the teachings of Alexander by incorporating a plurality of carriage assemblies in order to manipulate and control several nested instruments, such as wire, catheter and sheath assembly (as taught by Alexander) so that the user would learn the proper procedural steps for implementing a given medical procedure that requires the use of multiple medical instruments.

Therefore, the Examiner concludes that the above combination of the references is proper.

(2) Moreover, the rejected independent claims are amended to include an instruction set for modeling a color agent which calculates behavior of said color agent and keeps track of a position currently having enough concentration of contrast to be visualized, or a method or system for implementing the instruction set.

Because neither Anderson nor Alexander, whether considered alone or in combination, disclose or suggest the additional features recited in the amended claims, the rejection of the pending claims should be withdrawn.

- In response to argument (2), the Examiner respectfully disagrees. As already indicated in the above section (*Claim Rejections - 35 USC § 103*), Anderson does teach or suggest the claimed feature, "*instruction set for modeling a color agent which calculates behavior of said color agent and keeps track of a position currently having enough concentration of contrast to be visualized*". For instance the line, "The simulated syringe (3) can be used to simulate the injection of radioopaque dye, to simulate fluoroscopic imaging, or the delivery of a therapeutic agent or drug. Control parameters such as contrast injection volume and rate can be controlled by a user through a control interface such as a touch screen, enabling a user to choose the rate and total volume of injection. The injection process can be captured, and selected images of the process saved, to provide a roadmap image on a separate monitor" (Para.0107), describes that Anderson's system implements a program subroutine for modeling and controlling various parameters of a contrast fluid (such as injection volume and rate of flow) in order to provide or display a roadmap images for a given medical procedure (also see Para.0202).

Therefore, the Examiner concludes that Applicant's currently presented claimed features have already been taught or suggested by the prior art.

- With regard to claim 29, a new grounds of rejection has been established in this current office action due to the amendment made to the claim; and therefore, Applicant's arguments are now moot in views of the new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruk A. Gebremichael whose telephone number is (571) 270-3079. The examiner can normally be reached on Monday to Friday (7:30AM-5:00PM) ALT. Friday OFF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on (571) 272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bruk A Gebremichael/
Examiner, Art Unit 3715

/XUAN M. THAI/

Supervisory Patent Examiner, Art Unit 3715